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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,919	05/10/2001	Qingsheng Zhu	279.330US1	4736

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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,919	ZHU ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/17/03 (Amendment)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. Claims 1-3, 6-8, 10-14, 16, 17 and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) in view of Dev et al. (US 6347247) and further in view or Eggers et al. (US 4998933).

Chekanov discloses a method of prevention and treatment of atherosclerosis in blood vessels, including the coronary artery (col. 9 @ 10-13). The implantable generator (25) (col. 2 @ 25-34) includes therapy circuits and one or two leads (col. 3 @ 42-49) to create the low-frequency non-excitatory electrical field that prevents plaque build-up in the coronary artery of the heart muscle.

Chekanov discloses the claimed invention except for:

- the lead including an electrode patch (claims 2 and 12),
- spacing the electrical fields about 10 seconds apart (claims 6 and 17), and
- the lead having two electrodes (claims 7 and 14).

Dev et al. disclose a device to dilate vessels using electrical fields to prevent plaque build-up (col. 2 @ 47-51; col. 6 @ 21-27) and teach that it is known: 1) to apply the method to the coronary artery, using an exo-luminal electrode (known in the cardiac art as related to the heart to optionally be an electrode patch) to establish the electrical field, 2) to space the electrical fields about 10 seconds apart, and 3) to provide two electrodes. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of prevention and treatment of atherosclerosis in a blood vessel as taught by Chekanov, with the following elements as taught by Dev et al.:

- the lead including an electrode patch (claims 2 and 12) read as exo-luminal placement of the electrode in the heart for treatment of the coronary artery (col. 6 @ 28-35) to provide an electrode that enable creation of a broad electrical field enabling treatments of large areas of cardiac tissue,
- spacing the electrical fields about 10 seconds apart (claims 6 and 17) (c 7 @ 45-46) where one second or longer is read as about 10 seconds, to have a pulse timing sequence that is effective in treating plaque build-up, and
- the lead having two electrodes (claims 7 and 14) (col. 8 @ 59-64) to enable versatility in the creation of the electrical field.

Modified Chekanov discloses the claimed invention except the electrode field being generated such that the electrical field does not interfere with the heart rhythm.

Eggers et al. teach creating current flow along flux lines using stimulation that does not interfere with the natural pacing of the heart for the purpose of treating plaque safely. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stimulation that does not interfere with the natural pacing of the heart in the modified Chekanov system in order to reduce the plaque in the heart while avoiding the creation of arrhythmias that lessen cardiac efficiency and potential create life threatening conditions (col. 3 @ 38-45; col. 6 @ 43-54).

The Applicant's arguments filed 7/17/03 have been fully considered but they are not convincing.

In response to the Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Applicant asserts the following elements are not taught by Chekanov, Dev et al. and Eggers et al.: generating the electrical field includes outputting a non-excitatory electrical field such that the electrical field does not interfere with the heart rhythm. The Examiner disagrees. Chekanov discloses an implantable generator (figure 1 – (26); col. 2 @ 25-28) generating an electrical field (col. 1 @ 3 @ 42-49). The Applicant's specification teaches a non-excitatory electric field in the range 30 to 60 pulses per minute (page 7, line 23) and Chekanov teaches stimulation in the range of 30 to 120 beats per minute (col. 2 @ 66-67). Eggers et al. teach using treatment that does not interfere with the heart rhythm, hence Chekanov is modified to ensure the generated electrical field does not interfere with the heart rhythm (col. 3 @ 36-45).

The Applicant asserts Chekanov teaches away from the present invention because Chekanov teaches muscle stimulation (col. 2 @ 20-21). The Examiner disagrees. Chekanov teaches stimulating the muscle to contract and teaches generating an electrical field about the blood vessel (col. 2 @ 20-22). The generation of the electrical field is the teaching applied in this rejection.

As to clarification about vessel dilation using electrical fields to prevent plaque build-up, Dev et al. teach increasing the flow of fluid through a vessel by applying an electrical impulse (col. 2 @ 46-51), the impulse creating an electric field to induce vasodilation (col. 3 @ 15-22). Plaque can be removed/ denuded as part of the treatment process (col. 2 @ 61-65;

col. 6 @ 42-61), hence removing/ reducing the size of the site for plaque agglomeration and ultimately preventing/ reducing plaque build-up.

As to the Eggers et al. teachings, Eggers et al. teach creating current flow along flux lines (col. 6 @ 51-54) using stimulation that does not interfere with the natural pacing of the heart (col. 3 @ 41-42) for the purpose of treating plaque (col. 6 @ 45 and 50-51) safely so the natural pacing of the heart is not altered, creating potentially life threatening arrhythmias.

The rejection of record stands.

2. Claims 4, 5, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) in view of Dev et al. (US 6347247) and further in view or Eggers et al. (US 4998933) and further in view of Halsuka et al. (US 4830006). As discussed in paragraph 1 of this action, modified Chekanov discloses the claimed invention except for sensing a heart rhythm and generating a non-excitatory electrical field after the heart depolarization.

Haluska et al. teach heart signal sensing and cardiac stimulation using a sensing amplifier (25) and pacing section (31) for the purpose of determining the periods of the heart cycle, such as the refractory period and delivering appropriately timed stimuli. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a sensing amplifier and timed stimulation in the modified Chekanov et al. system in order to identify refractory periods, where stimulations are not conducted through the cardiac tissue, so the plaque prevention treatment is delivered in the refractory period/ after the heart depolarization, ensuring that the natural heart pacing is not interrupted (figure 6; col. 2 @ 42 – col. 3 @ 4).

3. Claims 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) and in view or Eggers et al. (US 4998933) and further in view of Haluska et al. (US 4830006).

Chekanov discloses a method of prevention and treatment of atherosclerosis in the coronary blood vessels and teaches the use of a pulse generator that includes therapy circuits and a system that includes one or two leads to create an electrical field to prevent plaque build-up (col.2 @ 13-16; col. 3 @ 42-49; col. 9 @ 10-13).

Chekanov et al. disclose the claimed invention except the electrode field being generated such that the electrical field does not interfere with the heart rhythm.

Eggers et al. teach creating current flow along flux lines using stimulation that does not interfere with the natural pacing of the heart for the purpose of treating plaque safely. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stimulation that does not interfere with the natural pacing of the heart in the modified Chekanov system in order to reduce the plaque in the heart while avoiding the creation of arrhythmias that lessen cardiac efficiency and potential create life threatening conditions. (col. 3 @ 38-45; col. 6 @ 43-54).

Modified Chekanov et al. disclose the claimed invention except for the pulse generator including a heart sensing unit.

Haluska et al. teach the cardiac cycle periods, heart signal sensing and cardiac stimulation using a sensing amplifier (25) and a pacing section (31) for the purpose of determining the periods of the heart cycle, such as the absolute and relative refractory periods, and delivering appropriately timed stimuli. It would have been obvious to one having ordinary

skill in the art at the time of the invention to have used an understanding of the absolute and relative refactory periods, a sensing amplifier, and timed stimulation in the modified Chekanov et al. system in order to identify periods where cardiac conduction varies, so the plaque prevention treatment can be delivered and/ or adjusted for the absolute and relative refractory periods /after the heart depolarization, ensuring natural heart pacing is not interrupted and gaining benefit from the optimized intensity of treatment (figure 6; col. 2 @ 42 – col. 3 @ 4).

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

8-28-03

Angela D. Sykes

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